



## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/077,194	12/04/1998	MANFRED BOHN	02481.1596	5713

7590

07/18/2002

FINNEGAN HENDERSON FARABOW  
GARRETT AND DUNNER  
FRANKLIN SQUARE BLDG SUITE 700  
1300 I STREET N W  
WASHINGTON, DC 200053315

EXAMINER

KIM, VICKIE Y

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 07/18/2002

36

Please find below and/or attached an Office communication concerning this application or proceeding.

RECEIVED

JUL 22 2002

FINNEGAN, HENDERSON,  
FARABOW, GARRETT & DUNNER, L.L.P.

Docketed

Case

Due Date

Action

By

Attorney

07-22-02

# Office Action Summary

Application No.

09/077,194

Applicant(s)

BOHN ET AL.

Examiner

Vickie Kim

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 39-42,48 and 53-66 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 39-42,48 and 53-66 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

**DETAILED ACTION**

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 38-39, 41-42, 48, 53-54 and 56-66 are rejected under 35 U.S.C. 102(b)/103(a) as being obvious over Lange(US 5,132,107) alone, if necessary, in view of Durrant et al(US 4,699,924).

Lange teaches a two phase shampoo wherein the first phase consists of a detergent composition and the second phase separated from the first phase comprises a physiologically acceptable acid component and an antimycotic, see abstract. At column 5, lines 15-65, the phase II composition has pH of 3-6, preferred 4-5 and contain an effective antimycotic compound(i.e. piroctone olamine) because of its anti-seborrheic effect. It further teaches that it can be combined with an organic acid(e.g. salicylic, lactic acid) beneficially and adjuvants such as rinsing agent . It clearly states that phase I composition has detergent effect whereas phase II composition has specific therapeutic effects resulted from active component such as piroctone olamine. The instant claims read on a method of treating seborrheic dermatitis comprising a composition consisting essentially of at least one 1-hydroxy-2-pyrone of formula I and a surfactant wherein the composition has pH ranged from 4.5-6.5. Claim 39

Art Unit: 1614

requires a method of treating seborrheic dermatitis using the a composition comprising at least one 1-hydroxy-2-pyrone of formula I and a surfactant. Claim 41 requires 1-hydroxy-2-pyrone with octyl radical which is the compound taught by the cited reference(i.e. piroctone olamine). Claims 53-66 require an addition of keratolytic agent such as sulfur or salicylic acid, or lactic acid. Thus, Lange teaches most of the elements required by the claims except the surfactant. Even though Lange does not express the term "surfactant", it would have been obvious, however, to one of ordinary skill in the art to add a surfactant into the said Lange's second phase composition to enhance rinsing effects as suggested at column 6, lines 53-55.

In any event, Durrant teaches a antidandruff cream consisting essentially of OCTOPIROX as an active agent and surfactant(i.e. EMULSENE 1219). The pH of Durrant's patented composition could be adjusted, for example, to pH 4.5 with triethanolamine, see column 14, lines 50. Thus one would have been motivated to make an antidandruff composition useful in seborrheic dermatitis consisting essentially of (or comprising) at least antimycotic agent 1-hydroxy-2-pyrone of formula I and one or more surfactant(s) wherein the composition has pH ranged from 4.5-6.5, to increase the therapeutic effects because the antiseborrheic effect could be maximized after cleansing the skin and the combining this ingredients in one composition is well within the skilled level of the artisan having ordinary skill in the art, as evidenced by the Durrant. One would have been motivated to do so to make the cost-effective product when it

Art Unit: 1614

combines in one product and improve the compliance that leads to higher therapeutic effects. Especially as suggested in Lange(at column 6, lines 45-47), the second phase composition is packaged separately from the first phase composition and the method of treating seborrheic dermatitis could be achieved regardless the first phase composition, especially could be achieved by any cleansing activity in daily life.

3. Claims 40 and 55 are rejected under 35 U.S.C. 103(a) as being obvious over Lange(US 5,132,107) and Durrant et al(US 4,699,924), in further in view of Saint-Leger(US 5,650,145).

Claims 40 and 55 require 1-hydroxy-2-pyridone with cyclohexyl radical substitution in R4 position. Saint-Leger teaches that Octopirox or Ciclopirox is effectively used in the treatment of seborrheic dermatitis(see column 2, lines 29-32). Thus, it would have been obvious to one of ordinary skill in the art to substitute one to another as suggested by Saint-Leger. One would have motivated to so for better selection or accessibility, and to fit in one's preference.

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same (or similar) ingredients and share common utilities, and pertinent to the problem which applicant is concerning. MPEP 2141.01(a).

### ***Response to Arguments***

Art Unit: 1614

1. Applicant's arguments filed April 24, 2002 have been fully considered but they are not persuasive. In response to the applicant's argument wherein applicant alleged that dandruff is not seborrheic dermatitis, referred by Fitzpatrick's dermatology in General Medicine. However this examiner likes to point out that the reference(Fitzpatrick's dermatology of in general medicine-1999) submitted by applicant teaches that Seborrheic dermatitis is manifested by fluffy white dandruff(see page 8/17) and effectively treated by ciclopiroxolamine(see page 10/17). It also teaches that seborrheic dermatitis is eczema(synonym) where each patentee in the cited reference(supra) teaches their patented antidandruff composition is effective in eczema condition as well(see Durrant, for example). Thus applicant's argument is not persuasive.

### ***Conclusion***

2. All the pending claims are rejected.
3. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675. The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-3165 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Vickie Kim,  
Patent examiner  
July 14, 2002  
Art unit 1614



SHEP K. ROSE  
PRIMARY EXAMINER  
GROUP 1200